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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/463,890	04/28/2000	ULRICH H. KOSZINOWSKI	203640	6925

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EXAMINER	
SULLIVAN, DANIEL M	

ART UNIT	PAPER NUMBER
1636	

DATE MAILED: 07/05/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action Before the Filing of an Appeal Brief	**Application No.** 09/463,890	**Applicant(s)** KOSZINOWSKI ET AL.	
	Examiner Daniel M. Sullivan	**Art Unit** 1636	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 16 June 2006 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:
   a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
   b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

   Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ They raise the issue of new matter (see NOTE below);
   (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).
4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☒ Applicant's reply has overcome the following rejection(s): See Continuation Sheet.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: _____.
   Claim(s) objected to: *44,45,52,55,65 and 66*.
   Claim(s) rejected: *36,37,40-43,46-48,50,51,53,54,56-64 and 67-70*.
   Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☒ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08 or PTO-1449) Paper No(s). _____
13. ☒ Other: See Continuation Sheet.

Daniel M Sullivan, Ph.D.
Primary Examiner
Art Unit: 1636

Continuation of 5. Applicant's reply has overcome the following rejection(s):

Rejection of claims 43 and 44 under 35 USC §112, second paragraph, as indefinite in depending from a cancelled claim. Rejection of claims 71 and 72 is rendered moot by the cancellation thereof.

Continuation of 11. Does NOT place the application in condition for allowance because:

Claim Rejections - 35 USC § 102

Claims 36, 37, 40-43, 46-48, 50-51, 53-54, 56-64 & 67-70 **stand rejected** under 35 U.S.C. 102(a) as being anticipated by Messerle et al (PNAS USA, December 1997, Vol. 9, pages 14759-14763; see the entire reference) for the reasons set forth in the 3 March Office Action commencing at page 6 and herein below.

Claims 36, 48, 51, 54, 57-60, 63-64 and 67-69 **stand rejected** under 35 U.S.C. 102(e) as being anticipated by Horsburgh et al (U.S. Patent No. 6,277,621 B1, filed on 2/26/1998; see the entire patent) for the reasons set forth in the 3 March Office Action commencing at page 7 and herein below.

Claims 36, 43, 48, 51, 54, 57-60 & 63 **stand rejected** under 35 U.S.C. 102(a) as being anticipated by Delécluse et al (Proceedings of the National Academy of Sciences, USA. 7 July 1998, Vol. 95, pages 8245-8250; see the entire reference) for the reasons set forth in the 3 March Office Action commencing at page 9 and herein below.

Claims 37, 40-43 & 72 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Horsburgh et al (U.S. Patent No. 6,277,621 B1, filed on 2/26/1998; see the entire patent) in view of Messerle et al (Journal of Molecular Medicine, Vol. 74, No. 4, p.B8, 1996; see the entire reference) for the reasons set forth in the 3 March Office Action commencing at page 12 and herein below.

Applicant sought to overcome the rejection by filing a certified copy of the foreign priority application. With regard to determining whether claims in a US application should be afforded benefit of a foreign application filing date, MPEP 201.15 instructs:

> The most important aspect of the examiner's action pertaining to a right of priority is the determination of the identity of invention between the U.S. and the foreign applications. The foreign application may be considered in the same manner as if it had been filed in this country on the same date that it was filed in the foreign country, and the applicant is ordinarily entitled to any claims based on such foreign application that he or she would be entitled to under our laws and practice. The foreign application must be examined for the question of sufficiency of the disclosure under 35 U.S.C. 112, as well as to determine if there is a basis for the claims sought.

In the instant case, the claims are directed to a recombinant vector containing an infectious herpes virus genomic sequence and all or a portion of a bacterial artificial chromosome (BAC) sequence, wherein said all or a portion of the BAC sequence enables replication of the recombinant vector in a host cell. Upon reviewing the English translation of the priority document, the Examiner can find no support for a recombinant vector comprising an infectious herpes virus genomic sequence and "a portion of a BAC" wherein the portion of the BAC enables replication of the recombinant vector in a host cell.

The priority document does not contain literal support for a portion of a BAC as recited in the instant claims. The closest teaching is found in the paragraph bridging pages 3-4 of the translation and reads as follows:

> The cloning vehicle is preferably a plasmid, e.g. the plasmid pRP2 or pRP3, as described below. Any vehicle is suitable, which together with the DNA to be cloned may form an artificial ring chromosome, such as a bacterial chromosome (BAC). Suitable cloning vehicles are low-copy vectors, since the stability of the cloned DNA is only ensured by the low number of copies of the plasmids. Further suitable vehicles are derivatives that are derived from the known mini-F-plasmids of E. coli. The mini-F-plasmid contains the bacterial genes (functions) repE (for the replication), par A, B, C (for the distribution of the plasmid on daughter bacteria and the strict supervision of the number of copies) ovi_s (origin of replication, for the replication).

Thus, the priority application contemplates plasmid or other vehicles, "which together with the DNA to be cloned may form an artificial ring chromosome, such as a bacterial chromosome (BAC)". As the skilled artisan would view plasmids and other cloning vehicles as typically comprising sequences other than those that merely enable replication in a host cell (e.g., selectable markers genes, the par A, B, C genes, etc.), the teaching does not provide implicit support for a vehicle defined only as being a portion of a BAC that enables replication in a host cell.

Furthermore, the passage cited above would convey to the skilled artisan that a BAC is viewed in the foreign application as the combination of the bacterial plasmid and the insert sequence. In contrast, the instant application appears to view a "BAC" as an entity separate from the insert. For example, originally filed claim 1 reads, "Recombinant vector containing infectious viral genome sequences having a size larger than 100 kb, as well as sequences of a cloning

vehicle which are capable of DNA replication in a host cell, with the cloning vehicle being a bacterial artificial chromosome (BAC)." (Emphasis added.)

Thus, the scope of the limitation "BAC" as contemplated in the priority application is not the same as the scope of a "BAC" as contemplated in instant application. In view of this and the fact that the insert comprised by the BAC is an infectious viral genomic sequence (i.e., also comprises sequences that enable replication of the vector in a host cell), the scope of "a portion of a BAC [that] enables replication of the recombinant vector in a host cell" would encompass subject matter of substantially different scope depending upon whether one views the scope of a BAC as encompassing only the cloning vehicle—as in the instant application—or views a BAC as encompassing the cloning vehicle and the infectious viral insert—as in the priority application. For this reason, even if the priority application had contemplated a vector delimited as comprising "a portion of a BAC [that] enables replication of the recombinant vector in a host cell", the scope of such a limitation would be substantially different when viewed in light of the disclosure of the priority application.

In view of the foregoing, the skilled artisan would conclude that the priority application does not provide descriptive support for the subject matter presently claimed sufficient to meet the requirements of 35 USC §112, first paragraph. Therefore, the claims are not entitled to benefit of the priority application.

Continuation of 13. Other:

Sequence Compliance

Applicant is again urged to submit an amendment directing entry of the "Sequence Listing" filed 1 September 2005 into the specification. Applicant is directed to the "Notice to Comply with Requirements for Patent Applications Containing Nucleotide Sequence and/or Amino Acid Sequence Disclosures" attached to the Office Action mailed 21 June 2001 (a copy of which is attached hereto), which states, "Applicant must file the items indicated within the time period set the Office action to which the Notice is attached to avoid abandonment under 35 USC §133" (¶1) and under the heading "Applicant must provide:", "An initial or substitute paper copy of the 'Sequence Listing', as well as an amendment directing its entry into the specification." (Emphasis added.)